

REMARKS

Reconsideration of the above-identified application is requested. Claims 1-26 are being presented without amendment

Rejection of claims 1-4, 6-8 and 26 under 35 U.S.C. §102(e)

Applicants respectfully traverse the rejection of claims 1-4, 6-8 and 26 under 35 U.S.C. §102(e). The Examiner takes the position that Silver et al. disclose a composition that comprises Aliskiren formulated into a microemulsion wherein the microemulsion comprises one or more organic solvent(s). Applicant respectfully traverses this position.

What Silver et al actually discloses is a microemulsion as a coating, envelope or protective matrix for sustained release dosage forms such as indwelling devices for local administration. Silver says nothing at all about a pharmaceutical composition for oral administration such as that of the present invention.

Accordingly, since Silver does not disclose all the elements of the claimed invention and therefore the rejection under 35 U.S.C. §102(e) have been traversed and should be removed.

Rejection of claims 5 and 9-25 under 35 U.S.C. §103(a)

Claims 5 and 9-25 have been rejected under 35 U.S.C. §103(a) over Silver (above) as applied to claims 1-4, 6-8 and 26 above in view of Owen et al (US Pat. 5,633,226), the Examiner taking the position that "it would have been obvious to modify the microemulsion of Silver with the microemulsion of Owen et al because Owen et al teach the advantages of convertible microemulsions that provide for significantly increased bioavailability of the delivered active agent at the desired location". Applicant respectfully traverses this position.


Owen is directed mainly at the formulation of peptides and proteins not small molecules. To say it would be obvious to use this disclosure to formulate a rennin inhibitor into a microemulsion preconcentrate is to clearly use impermissible hindsight. Formulations for proteins and peptides are clearly very different endeavors and require different knowledge and to formulate one does not mean one of ordinary skill in the art would be able to arrive at the presently claimed invention.

Therefore, Owen does not compensate for the insufficiencies of Silver and the present invention is not rendered obvious by a combination of Silver and Owen and the rejection 35 U.S.C. §103 has been overcome and should be withdrawn.

In view of the foregoing, Applicant submits the Application is now in condition for allowance and respectfully requests early notice to that effect.

Respectfully submitted,

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